

Remarks

Amendments

Claims 1, 9, 13, and 21 have been amended to recite one or more isolated *mutans streptococci* strains, wherein the *mutans streptococci* strains are lactate dehydrogenase-deficient. Support for the amendments can be found in, *inter alia*, claims 24-27. Claims 3, 5, 10, 11, 14, 15, and 28 have been amended to change their dependency. These are not narrowing amendments. Claims 3, 5, 10, 11, 14, and 15 have been amended to recite the plural form of streptococcus. These are not narrowing amendments. Claim 3 has been amended to recite strain “*S. rattus* JH145 (*ldh*, *str*).” Support for the amendment can be found in the specification at, *inter alia*, page 17, last paragraph. Claims 24-27 have been cancelled. New claim 30 has been added. Support for the claim can be found in the specification at, *inter alia*, last paragraph of page 15. New claim 31 has been added. Support for the claim can be found in the specification at, *inter alia*, page 8, line 13. A fee of \$110 for an extra independent claim in excess of three is filed herewith.

Amendments and cancellations to the claims are made without prejudice or disclaimer. They are fully supported by the specification as filed and do not introduce new matter. Additionally, these amendments and cancellations are not and should not be construed as admissions regarding the patentability of the claimed or canceled subject matter. Applicants reserve the right to pursue the subject matter of previously presented claims or any broader claims in this or in any other appropriate patent application. Accordingly, Applicants respectfully request the entry of the amendments presented.

Interview Summary

A telephonic interview was conducted between the undersigned and Examiner Ware on September 24, 2009. No exhibits were shown and no demonstrations were conducted. All pending claims were discussed. No prior art was discussed. The propriety of the restriction requirement was discussed. The Examiner indicated that the restriction requirement would be, at least in part, reconsidered if the claims were amended to include the strains of bacteria in each set of composition claims. No other pertinent matters were discussed.

Restriction Requirement

As discussed during the interview claims with different preambles, but the same active steps are not properly restricted. *See, e.g.*, Biotechnology/Chemical/Pharmaceutical USPTO Customer Partnership Meeting, June 13, 2007, Bruce Campell presentation, www.cabic.com/bcp/061307/BCampell_RBPPI_r2.ppt. Page 7 of Mr. Campell's

presentation states that claims 1-3 below are not properly restricted where the claims require the same active step and the specification teaches that the outcomes are the same.

Claim 1. A method of reducing pain by administering compound ABC to a patient suffering from a cold.

Claim 2. A method of reducing fever by administering compound ABC to a patient suffering from a cold.

Claim 3. A method of reducing congestion by administering compound ABC to a patient suffering from a cold.

In the instant invention claim Groups I, II and III all recite the same active composition: one or more isolated *mutans streptococci* strains, wherein the *mutans streptococcus* strains are lactate dehydrogenase-deficient, one or more isolated *Streptococcus oralis* strains and one or more isolated strains of *Streptococcus uberis*. Only the preamble differ. In this case the compositions are not properly restricted. Furthermore, the methods of Group IV (claims 21-23) and claims 28-29 recite the same active steps of claims 17-20 (part of Group I) and are not properly restricted. Therefore, Applicants respectfully request that all claims be examined together in this application.

Finally, during the interview the Examiner requested confirmation that the streptococci mutans are a group of organisms. Yoo *et al.* teaches that “[m]utans streptococci are divided into seven species: *Streptococcus mutans*, *S. sobrinus*, *S. downei*, *S. rattus*, *S. cricetus*, *S. ferus*, and *S. macacae*.” See page 246, left col. first paragraph (copy attached).

Rejection of Claims 1-3, 5, 17-20, 24, and 28-29 Under 35 U.S.C. § 112, first paragraph

Claims 1-3, 5, 17-20, 24, and 28-19 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly lacking written description. Applicants respectfully traverse the rejection.

The Office asserts that the specification does not disclose a repeatable process to obtain the microorganisms recited in the claims and it is not apparent of the microorganisms are readily available to the public. The claims recite compositions comprising *Streptococcus oralis* strains, *Streptococcus uberis*, and lactate dehydrogenase-deficient *mutans streptococci* strains. Each of these strains is readily available to the public from, for example the American Type Culture Collection (Manassas, VA). For example, the ATCC sells the following *S. oralis* strains: ATCC 35037, ATCC 55229, ATCC 700233, ATCC 700234 and ATCC 9811 (see specification page 7, lines 3-5). The ATCC sells the following *S. uberis* strains: ATCC 13386, ATCC 13387, ATCC 19435, ATCC 27958, ATCC 35648, ATCC 700407, ATCC 9927 (see specification page 7, first full paragraph). The ATCC sells the

following LDH-deficient *mutans streptococci* strains: *S. rattus* JH145 (ATCC 31377) and JH140 (ATCC 31341) (see specification page 8, first full paragraph). Furthermore, LDH-deficient *mutans streptococci* strains can be made using the methods disclosed in, for example, Hillman, Lactate dehydrogenase mutants of *Streptococcus mutans*: isolation and preliminary characterization. Infect. Immun. 21:206-212 (1978). See also, specification page 8, first full paragraph. Therefore, the microorganisms recited in the claims are readily available to the public and/or can be made using a repeatable process.

Applicants respectfully request withdrawal of the rejection.

Rejection of Claims 1-3, 5, 17-20, 24, and 28-29 Under 35 U.S.C. § 102(b)

Claims 1-3, 5, 17-20, 24, and 28-19 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by EP0058575. Applicants respectfully traverse the rejection.

Amended claims 1, 9, 13, and 21 recite one or more isolated *mutans streptococci* strains, wherein the *mutans streptococci* strains are lactate dehydrogenase-deficient. Anticipation under 35 U.S.C. § 102 requires the presence in a single prior art disclosure of each and every element of a claimed invention. *Lewmar Marine Inc. v. Barient Inc.*, 827 F2d 744, 747 (Fed. Cir. 1987); 3 USPQ2d 1766, 1767 (Fed. Cir. 1987). EP0058575 does not teach or suggest a composition comprising one or more isolated *mutans streptococci* strains, wherein the *mutans streptococci* strains are lactate dehydrogenase-deficient. Therefore, EP0058575 cannot anticipate the claims. Applicants respectfully request withdrawal of the rejection.

Rejection of Claims 1-3, 5, 17-20, 24, and 28-29 Under 35 U.S.C. § 102(b)

Claims 1-3, 5, 17-20, 24, and 28-29 stand rejected under 35 U.S.C. § 102(b) as allegedly obvious over EP0058575 in view of Tagg. Applicants respectfully traverse the rejection.

The Office asserts that Tagg *et al.* teach compositions and methods therefore, wherein the composition comprises a mixture of *S. oralis* and *S. uberis*, and including, optionally, other bacteria, such as *S. mutans*. Tagg, however, does not teach, suggest or even mention *S. uberis*. Additionally, Tagg only teaches *S. oralis* in a mixture of *S. sanguis* and *S. mitis*. See Table 1; page 220, left col. Neither EP0058575 nor Tagg teach the specific combinations of the invention.

The Office also asserts that “[e]ach of the bacteria are disclosed independently in the art to be useful for the same type of treatments. . . .” Each bacterium or group of bacteria, however, is taught to be useful for different types of treatments. See *e.g.*, Tagg, Table 1.

EP0058575 and Tagg do not teach or suggest the specific combination of bacteria presently claimed in the instant invention. Therefore, the claims are not obvious over these references. Applicants respectfully request withdrawal of the rejection.

Respectfully submitted,

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Reg. No. 43,673
217-239-1962